

ISO 10993-1:2025-11 (E)

Biological evaluation of medical devices - Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process

Contents

Page

Foreword.....	v
Introduction	vii
1 Scope	1
2 Normative references	2
3 Terms and definitions	2
4 General principles	8
4.1 Biological evaluation within the ISO 14971 risk management framework.....	8
4.2 Biological evaluation process.....	10
4.3 Medical device life cycle.....	11
4.4 Animal welfare	12
5 Biological evaluation plan	12
6 Biological risk analysis	13
6.1 General approach	13
6.2 Identification of characteristics related to biological safety	14
6.3 Identification of biological hazards, biologically hazardous situations and potential biological harms.....	14
6.4 Categorization of medical device and determination of scope of evaluation.....	16
6.4.1 General	16
6.4.2 Exposure duration categories	16
6.4.3 Calculation of exposure duration for categorization of medical devices.....	17
6.4.4 Body contact and biological effects for consideration.....	18
6.5 Biological effects for evaluation.....	21
6.5.1 Overall approach	21
6.5.2 Cytotoxicity.....	21
6.5.3 Sensitization.....	22
6.5.4 Irritation.....	22
6.5.5 Systemic toxicity	22
6.5.6 Local effects after tissue contact.....	23
6.5.7 Genotoxicity.....	23
6.5.8 Carcinogenicity.....	23
6.5.9 Haemocompatibility	24
6.5.10 Other biological effects.....	24
6.5.11 Other factors to be considered	25
6.6 Gap analysis	28
6.6.1 General	28
6.6.2 Medical devices evaluated using previous versions of this document	28
6.7 Biological equivalence	28
6.8 Testing.....	30
6.8.1 General principles	30
6.8.2 Biological, physical and chemical testing.....	31
6.8.3 Degradation testing.....	32
6.8.4 Toxicokinetic studies.....	32
6.9 Biological risk estimation.....	33
7 Biological risk evaluation.....	33

8	Biological risk control	34
9	Biological evaluation report	34
10	Production and post-production activities	34
Annex A (informative)	Material selection and characterization to support the biological evaluation of a medical device	36
Annex B (informative)	Rationale for key changes in the biological effects listed in Tables 1 to 4	39
	Bibliography	41